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| 10/806,531 | 03/23/2004 | David Feygin | 115-003US | 4765 |
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| EXAMINER | | | | |
| HU, KANG | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3715 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/806,531

Applicant(s)

FEYGIN ET AL.

Examiner

KANG HU

Art Unit

3715

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8,10,12,15-17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8,10,12,15-17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Current office action is in response to amendment filed on 6/23/2008. Claims 2-3, 7, 9, 11, 13-14, 18, 20-28 have been cancelled. Currently Claims 1, 4-6, 8, 10, 12, 15-17, and 19 are pending in the application. Specification amended on 6/23/2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 4-6, 8, 10, 12, 15-17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al (US 6,470,302 B1) in view of Rosenberg et al. (US 5,821,920) and further in view of Grayzel (US 4,850,960).

Re claims 1 and 4, an apparatus comprising: a needle/catheter module (Cunningham, abstract "catheter needle assembly"), wherein the needle/catheter module comprises: a needle; a catheter, wherein said catheter receives said needle (Cunningham, col 5, lines 34-40, "the interface device includes a catheter unit assembly for receiving a catheter needle assembly"), Cunningham does not explicitly teach wherein at least one of said needle or said catheter comprise a bevel, Grayzel teaches of a catheter needle with a beveled tip, it would have been obvious to combine the teachings of Cunningham and Grayzel as they're both needle/catheter simulators and analogous art. Cunningham discloses of knowing Rosenberg teaches of a pen-like stylus allows for dexterous 3-dimensional manipulation, and the position and orientation of the stylus is

communicated to a host computer. The immersion Probe has six degrees of freedom which conveys spatial coordinates (x,y,z) and orientation (roll, pitch, yaw) of the stylus to the host computer. Although Rosenberg does not teach of sensor senses an orientation of the bevel, it is understood that the bevel of the catheter / needle is attached to the catheter / needle and therefore the orientation of the catheter/needle would also translate to the orientation of the bevel. It would have been prima facie obvious to combine the teachings of Rosenberg, as Rosenberg also teaches creating a realistic simulation environment of laparoscopic surgery and catheter insertion and has been discussed by Cunningham in the specification. Cunningham further teaches the added limitation of pseudo skin (mock skin), wherein said pseudo skin comprises an opening for receiving said needle and catheter. Cunningham discloses that mock skin is well known in the art by disclosing "model includes a mock bodily region of interest" (col 1, 59-60); "internal arterial modeling device" and "mock arterial paths" (col 2, 4-5). Cunningham further discloses the use of "skin traction mechanism" and "the computer system performs a simulation of the surface and subsurface anatomy of human skin" is also analogous to the use of mock skin (col 7, 5-7). Lastly Cunningham claims the use of mock skin in the claim language of claims 2 and 3. Rosenberg describes the use of skin for the same purpose (col 4, 62- 68).

Claim 5, Cunningham, Rosenberg and Grayzel does not explicitly teach that the sensor is physically coupled to said needle. Instead the sensor is located within the housing unit or the simulator.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to place the sensor coupled to the needle, because

Applicant has not disclosed that by coupling the sensor to the needle provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention, to perform equally well with either the sensor attached to the needle or to the housing unit because both would perform the same function of measuring the orientation of the needle and the catheter.

Therefore, it would have been prima facie obvious to modify Cunningham, Rosenberg, and Grayzel because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Rosenberg, Cunningham and Grayzel.

Claim 6, data processing system that receives a signal that is indicative of said orientation of said bevel (by sensing the orientation of the needle/catheter).

Claim 8, housing, wherein said receiver is disposed within said housing, and wherein said pseudo skin is substantially co-planar with a surface of said housing (skin traction mechanism of Cunningham).

Claim 10, Cunningham discloses the use of a force feedback assembly, wherein at least one of said needle and said catheter detachably couples to said force-feedback assembly (abstract).

Claims 12, 15-17, and 19 have the same features as claimed above and will not be repeated herein.

Response to Arguments

4. Applicant's arguments filed 6/23/2008 have been fully considered but they are not persuasive.

RE argument re claims 1 and 12, MPEP 2114 states APPARATUS CLAIMS MUST BE STRUCTUR-ALLY DISTINGUISHABLE FROM THE PRIOR ART

>While features of an apparatus may be recited either structurally or functionally, claims< directed to >an< apparatus must be distinguished from the prior art in terms of structure rather than function. >In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971);< In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore the argument by the applicant is not persuasive to overcome the prior art of reference.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KANG HU whose telephone number is (571)270-1344. The examiner can normally be reached on 8-5 (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on 571-262-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Kang Hu/
Examiner, Art Unit 3715

/XUAN M. THAI/
Supervisory Patent Examiner, Art Unit 3715